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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,434

02/15/2005

Rene Djurup

DJURUP1

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

GUDIBANDE, SATYANARAYAN R

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

03/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,434

Applicant(s)

DJURUP ET AL.

Examiner

SATYANARAYANA R.
GUDIBANDE

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27-38,40,53,54,57,58 and 73-81 is/are pending in the application.
- 4a) Of the above claim(s) 54,57,58,80 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 27-38, 53 and 74-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I invention (claims 1, 27-40, 53 and 73) and SEQ ID NO. 595 as species in the reply filed on 4/30/07 was acknowledged in the office action dated 6/19/07.

Prior art search for the SEQ ID NO: 595 indicated that the peptide sequence SEQ ID NO: 595 was found to be free of art. Search was extended and prior art was found for SEQ ID NO: 594. Applicants canceled the claim 39, corresponding to SEQ ID NO: 594. The prior art search was extended to other species in claims 28-38 and 40 and found them to be free of art. The search was extended to the generic formula of claim 1 and has been found to be free of art. However, the amended claim 1 present new matter as described below in the rejection.

New claims

Newly submitted claims 80 and 81 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims are drawn to method of treatment of gram negative bacterial infection. The bacterial infection can be treated by using an antibacterial drug such as penicillin and hence the invention of claims 80 and 81 would have been restricted out if presented earlier as claims drawn to a process that can be accomplished by a different compound other than the compounds claimed in the instant invention.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 80 and 81 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 27-38, 40, 53, 54, 57, 58 and 73-81 are pending.

Claims 54, 57, 58, 80 and 81 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 2-26, 39, 41-52, 55, 56 and 59-72 have been canceled.

Claims 1, 27-38, 53 and 74-79 are examined on the merit.

Any objections and rejections made in the previous office action dated 4/30/07 and not specifically mentioned here are considered withdrawn.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

Applicant's arguments, see page 6-8, filed 12/17/07, with respect to claims 1, 39, 53 and 73 have been fully considered and are persuasive. The rejection claims 1, 39, 53 and 73 of under 35 USC 102(b) has been withdrawn.

Claim Rejections - 35 USC § 112

Applicant's amendments to claim 1, see page 2-5, filed 12/17/07, have been fully considered and are persuasive. The rejection claims of 1, 39, 53 and 73 under 35 USC 112 second paragraph has been withdrawn.

New grounds of rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 27-38, 53 and 74-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim 1 has been amended to recite that the limitation,
“[w]herein, at least one of the following conditions applies:

- (a) X19 is Arg or Ala,
- (b) X9 is Pro, Arg, or Gln,
- (c) X19 is Gln and X1 includes Pro,
- (d) X19 is 2-5 amino acid residues, or
- (e) X10 is Asn or Gln”.

Lack of Ipsis Verbis Support

The specification lacks any Ipsis Verbis support that would support the limitation, “[w]herein, at least one of the following conditions applies:

- (a) X19 is Arg or Ala,
- (b) X9 is Pro, Arg, or Gln,
- (c) X19 is Gln and X1 includes Pro,
- (d) X19 is 2-5 amino acid residues, or
- (e) X10 is Asn or Gln” as recited in claim 1 of the amended claims.

The support for the proviso as originally disclosed specification and originally recited claims only supports the limitation “that when X1 includes Pro, then X19 is Gln” (page 12, line 4 of the specification). The additional conditions recited in the instant claims do not have literal support in the specification as originally filed.

Lack of Implicit Support

It is acknowledged that there is it should be noted, that exact terms need not be used *in haec verba* to satisfy the written description requirement of the first paragraph of 35 U.S.C. 112. Newly added claims or amendment can be supported by implicit, or inherent disclosure. However, the specification also lacks any implicit or inherent disclosure that one of the additional conditions as stated in the amended claims is supported, for e.g., if X19 is ‘Arg or Ala’, the condition does not further say that X1 need not include ‘Pro’ as required by the originally disclosed proviso and as claimed in the invention. Hence, the claim as recited does not have implicit support in the specification.

In conclusion, the specification does not provide reasonable support to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention as amended.

Applicant's amendment to claim 1 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Anish Gupta/
Primary Examiner, Art Unit 1654